DEPARTMENT OF HEALTH AND HUMAN SERVICES

95167d

Public Health Service
Food and Drug Administration
Central Region

New Jersey District
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 526-6010

WARNING LETTER

January 21, 2005

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Edward Kane
Chief Executive Officer
E-Lyte Incorporated
45 Reese Road
Millville, New Jersey 08332

05-NWJ-08

Dear Mr. Kane:

The Food and Drug Administration has reviewed your Internet website at the address: www.detoxxbox.com. Based on our review, we have found that your products the Detoxx Box, Evening Primrose Oil, Butyrate, Vitamin C, and the other products sold as components of the Detoxx Box are in violation of the Federal Food, Drug and Cosmetic Act (the Act). You can find the Act and implementing regulations on our Internet website at www.fda.gov.

Under the Act, articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man are drugs [section 201(g)(1)(B) of the Act]. The Internet labeling for your products listed above bears claims that cause these products to be drugs. Examples of such disease claims on your website include:

Evening Primrose Oil

Your website lists numerous studies that suggest that Evening Primrose Oil (EPO) is useful in treating diseases, such as atopic eczema, rheumatoid arthritis, MS (multiple sclerosis), and diabetes. The website also includes the following explicit disease claims:

- **"Atopic Eczema:** ... [A]dministration of GLA [gamma-linoleic acid] has been found to improve the clinically assessed skin condition and skin roughness of patients with atopic eczema. ..."
- **"Rheumatoid Arthritis and NSAIDS:** Belch and colleagues published a trial in which 49 patients suffering from rheumatoid arthritis (RA) received either a placebo or 1) EPO with a total of 540 mg of GLA per day .... Analysis showed that the nonsteroidal anti-inflammatory drugs (NSAIDs) could be reduced significantly in both experimental groups compared with the placebo group. ..."
- **"MS:** The most commonly used home treatment during the previous year was evening primrose oil ...."
- **"Diabetes and Evening Primrose Oil:** ...EPO treatment ... may have potential therapeutic relevance for diabetic microvascular complications...."

Butyrate

Your website lists numerous studies that imply that Butyrate is useful in treating or preventing diseases, such as cancer, and is useful as an anti-inflammatory and anti-bacterial. The website also includes the following explicit disease claims:

- **"Anti-bacterial:** Butyric acid ...is also known to inhibit bacterial growth, and may be a significant factor in controlling bacterial growth in the stomach of pre-weaned animals...."
- **"Anti-inflammatory:** [Butyrate's] ... anti-inflammatory properties provide a rationale for assessing butyrate in the treatment of Crohns Disease...."
- "Butyrate may be an important protective agent in colonic carcinogenesis."

Vitamin C

Your website lists numerous studies that imply that Vitamin C is useful in treating or preventing diseases such as high blood pressure and cardiovascular disease, and includes the following explicit disease claims:

- "High dietary intake of vitamin C may lower the risk of Alzheimer [sic] disease."
- "Low plasma vitamin C was associated with increased risk of stroke."
- "C helped me manage my lifelong struggle with allergies and I quickly dropped those pesky allergy shots."
- "Our results support a role for vitamin C in diminishing the risk of cortical cataracts in women aged <60 y..."

Your website also includes claims in the form of case studies that suggest that the Detoxx Box and its components are intended for use to treat or cure diseases such as ALS, autism, Lyme disease, and multiple sclerosis.

These claims causethese products to be drugs as defined in section 201(g)(1)(B) of the Act. Because the products are not generally recognized as safe and effective when used as labeled, they are also new drugs as defined in section 201(p) of the Act. Under section 505 of the Act, a new drug may not be legally marketed in the United States without an approved New Drug Application (NDA).

The above violations are not meant to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that products marketed by your firm comply with all the requirements of the Act and its implementing regulations.

You should take prompt action to correct these violations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure and injunction.

We have received your June 18, 2004 response to the FDA-483, List of Inspectional Observations, issued to your firm by New Jersey District investigators at the conclusion of the inspection they conducted from May 6 through June 4, 2004. We will make your response part of our official files. The corrective actions you have outlined in the response, if completed, appear to be adequate to address the issues raised during the inspection; however, the additional violations discussed in this letter must be addressed.

During the inspection of your firm investigators obtained copies of The Detoxx Book, which describes a number of case studies of specific diseases, such as Lyme disease, chronic

fatigue syndrome, fibromyalgia, and multiple sclerosis. Your website states that "[t]he Book, ... and the Detoxx Box (the nutrients) are an exciting step forward in treating a large group of very difficult disorders as Lyme, CFS, MS, Fibromyalgia, Sick Building Syndrome, ALS, Parkinson's, Autism, Internal Bowel Disease... and many others." The book lists the treatment plan for these patients, which include your products such as BodyBio Balance oil, carnitine, and primrose. If this book "accompanies" your products (which can refer either to physical accompaniment or a textual relationship), it is considered labeling for the products and would also cause them to be drugs.

Investigators also obtained copies of your product labels during the inspection. Based on the presence of a "Supplement Facts" panel on these labels, your Evening Primrose Oil, Butyrate, and Vitamin C products appear to be represented as dietary supplements. However, the principal display panel of a dietary supplement must identify the products using the term "dietary supplement" or a similar allowable term in accordance with section 403(s)(2)(B) of the Act (see 21 CFR 1013(g)). If you wish to market these products as dietary supplements, you should revise your labels in accordance with this requirement, if you have not already done so.

Please notify this office within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Your response should be sent to Sarah A. Della Fave, Compliance Officer, U.S. Food & Drug Administration, New Jersey District, 10 Waterview Boulevard, 3rd Floor, Parsippany, New Jersey 07054.

Sincerely,

Douglas I. Ellsworth
District Director
New Jersey District

cc: Mr. Anthony Vitullo
President
E-Lyte Incorporated